

What is claimed is

1. An implantable balloon comprising:  
a valve portion having:  
  
a valve body defining an inlet;  
  
a valve stem extending from said body opposite said inlet;  
  
a piercing extending from said inlet, through said body and said stem, said valve portion constructed from a soft, elastomeric material having memory thereby causing said piercing to remain closed and fluid-tight unless penetrated by a relatively rigid member;  
  
a balloon portion, integral with said valve portion, constructed and arranged to receive and hold fluids exiting said piercing opposite said inlet.
2. The balloon of claim 1 wherein said valve stem comprises at least one side.
3. The balloon of claim 1 wherein said valve stem comprises a rounded tip.
4. The balloon of claim 1 wherein said valve stem comprises a side and said valve portion further has a sidewall, laterally displaced from said valve stem side, and integral with an inside surface of said balloon portion.
5. The balloon of claim 1 wherein said valve portion is substantially cylindrical.
6. The balloon of claim 1 wherein said valve body, said valve stem, and said inlet are substantially cylindrical and substantially concentric.
7. The balloon of claim 1 wherein said valve stem comprises at least one side and said piercing extends through said side of said stem.

8. The balloon of claim 1 wherein said valve stem comprises a side and said valve portion further has a sidewall extending from said valve body, laterally displaced from said valve stem side.

9. The balloon of claim 8 wherein said valve body forms a curved web, integrally connecting said valve portion sidewall with said valve stem side, said curved web being concave and opening toward said balloon portion.

10. The balloon of claim 1 wherein said soft, elastomeric material comprises silicone.

11. A self-sealing medical balloon of unitary construction, implantable in a human body, comprising:

- a cylindrical valve body having a predetermined diameter and an upper side and a lower side;
- an inlet defined by said valve body lower side;
- a cylindrical valve stem extending upwardly from said valve body, said valve stem having a diameter smaller than said valve body diameter;
- a balloon wall extending upwardly from said valve body, said balloon wall having an inner diameter, while in a deflated state, which is larger than said valve stem diameter such that an annular space exists between said balloon wall and said valve stem while said balloon is deflated, said annular space provided to relieve stress from a union of said balloon wall and said valve body when said balloon is inflated;
- a piercing extending from said inlet, through said valve body and through said valve stem, into an inner chamber defined by said balloon, said piercing constructed and arranged to remain closed unless a substantially rigid member is pushed through said piercing, such as to inflate said balloon,

*and concave* whereby said piercing recloses after said member is withdrawn, thereby preventing a fluid from escaping from said inner chamber.

12. The balloon of claim 11 whereby said inlet, said valve body, and said valve stem are substantially concentric, sharing a common longitudinal axis.
13. The balloon of claim 12 whereby said piercing follows said longitudinal axis.
14. The balloon of claim 12 whereby said piercing comprises a curved portion.
15. The balloon of claim 12 whereby said piercing comprises a straight portion and a curved portion, said straight portion extending upwardly from said inlet and substantially parallel to said axis, said curved portion extending from said straight portion to a side of said valve stem.
16. The balloon of claim 11 wherein said annular space is defined on a lower side by a curved web which is concave and opening upwardly.
17. The balloon of claim 11 wherein said balloon is constructed entirely of silicone.
18. The balloon of claim 11 further comprising a removable skirt extending downwardly from said valve body, said skirt providing a surface which may be handled during a balloon manufacturing operation without damaging said balloon wall, or said valve body.
19. The balloon of claim 18 wherein said removable skirt has an outside diameter smaller than an outside diameter of said valve body such that a ridge is formed between said valve body and said skirt.
20. A method of forming a medical balloon, implantable into a human body, comprising:

providing a valve portion having a body, an elongate cylindrical sidewall extending from said body, and an end portion extending from said sidewall, said end portion defining an opening, said valve portion constructed of a first material;

dipping said end portion into a pool of a second material in molten form such that said opening enters first, thereby forming a meniscus over said opening when said valve portion is removed from said pool;

removing said end portion from said pool;

allowing said meniscus to harden such that said meniscus becomes integral with said end portion;

dipping said valve portion into said pool to form a layer of material over said sidewall;

removing said valve portion from said pool;

allowing said layer to harden;

repeating the steps of dipping a second predetermined length, removing, and allowing said layer to harden, until a desired thickness of material has formed over said sidewall.

21. The method of claim 20 wherein the step of dipping said end portion into a pool of a second material further comprises dipping said end portion into a pool of a second material which is the same as the first material.

22. The method of claim 20 wherein the step of providing a valve portion comprises providing a valve portion having an end portion which curves inwardly to define said opening, such that an inside diameter of said opening is smaller than an inside diameter

of the cylindrical portion, said end portion constructed and arranged to form a meniscus when dipped into said pool.

23. The method of claim 20 further comprising piercing said valve body with a sharpened, needle-like implement, thereby forming a self-sealing piercing capable of directing a rigid member from outside said balloon to inside said cylindrical sidewall without imparting damage to said valve body.

24. The method of claim 23 wherein said step of piercing said valve body comprises:

pushing said implement into said valve body, opposite said cylindrical sidewall, a predetermined distance which is less than a distance required to push said implement through said valve body and into an open chamber defined by said cylindrical sidewall;

bending said valve body;

pushing said implement further until said implement enters said chamber, thereby forming a curved portion in said piercing due to said bending.

25. The method of claim 20 wherein providing a valve portion comprises providing a valve portion having a skirt extending therefrom in a direction opposite said sidewall, useable to grip said valve portion while forming said balloon.

26. The method of claim 25 further comprising removing said skirt after said desired thickness of material has formed over said sidewall.

27. The method of claim 26 wherein removing said skirt comprising cutting said skirt off of said body.

28. The method of claim 20 wherein providing a valve portion comprises molding said valve portion.

29. The method of claim 20 wherein providing a valve portion comprises providing a valve portion having a cylindrical sidewall extending from said body, said sidewall having a lower sidewall with an outer diameter substantially equal to an outside diameter of said valve body, and an upper sidewall having an outer diameter which is smaller than that of the lower sidewall, thereby forming a taper between said upper sidewall and said lower sidewall, said taper constructed and arranged to allow expansion of said balloon wall after said balloon has been initial inflated and deflated.

30. The method of claim 25 wherein dipping said valve portion into said pool comprises dipping said valve portion into said pool until said valve portion is submerged and said skirt remains masked from said pool.

31. The method of claim 20 further comprises repeating said steps of dipping said end portion, removing said end portion from said pool, and allowing said meniscus to harden until a desired meniscus thickness has been achieved before performing said step of dipping said valve portion into said pool to form a layer of material over said sidewall.

32. The method of claim 20 wherein the step of allowing said layer to harden comprises spinning said valve portion around a central, longitudinal axis, for a predetermined time.

33. The method of claim 20 further comprising vulcanizing said meniscus prior to dipping said valve portion into said pool.

34. The method of claim 33 wherein vulcanizing said meniscus comprises placing said valve portion into an oven at a predetermined temperature for a predetermined time.

35. The method of claim 34 wherein said predetermined temperature is less than 170C

36. The method of claim 34 wherein said predetermined temperature is greater than 150C

37. The method of claim 34 wherein said predetermined temperature is approximately 160C

38. The method of claim 34 wherein said predetermined time is greater than 5 minutes.

39. The method of claim 34 wherein said predetermined time is less than 20 minutes.

40. The method of claim 34 wherein said predetermined time is greater than 9 minutes.

41. The method of claim 34 wherein said predetermined time is less than 11 minutes.

42. The method of claim 20 further comprising vulcanizing said medical balloon after said desired thickness of material has formed over said sidewall.

43. The method of claim 42 wherein vulcanizing said balloon comprises heating said balloon to a predetermined temperature for a predetermined time.

44. The method of claim 43 wherein said predetermined temperature is greater than 150C.

45. The method of claim 43 wherein said predetermined temperature is less than 170C

46. The method of claim 43 wherein said predetermined temperature is approximately 160C

47. The method of claim 43 wherein said predetermined time is approximately 1 hour

48. The method of claim 20 further comprising performing an inflation test.

49. The method of claim 48 wherein performing said inflation test comprises inflating said balloon with a fluid, inspecting said balloon for leaks, and deflating said balloon

50. The method of claim 48 further comprising oven baking said balloon after said inflation test is completed.

51. The method of claim 35 wherein said step of oven baking comprises placing said balloon in an oven at approximately 90C for approximately 60 minutes.

52. A valve of unitary construction, useable to prevent fluid from escaping from an implantable balloon operably attached to the valve, the valve comprising:

- a substantially cylindrical body defining an inlet, concentric with said body, opening in a direction opposite the balloon;
- a valve stem, integral with said body, having a substantially cylindrical side and rounded tip opposite said body and leading to an interior of the balloon;
- a piercing, defined by said valve body and said valve stem, extending from said inlet toward said balloon and leading to the interior of the balloon, said piercing having a bend which curves toward said stem side;
- a cylindrical sidewall, integral with said body, extending in a direction toward said balloon, radially displaced from said stem side, thereby creating an annular space between said stem and said sidewall, said sidewall having an external surface attachable to said balloon.

53. The valve of claim 52 wherein said body further defines a curved portion, concave so as to open toward said balloon interior, connecting said sidewall with said stem.

54. The valve of claim 52 further comprising an end portion, integral with and extending from said sidewall, which curves inwardly to define an opening having an inner diameter which is smaller than an inner diameter of said cylindrical sidewall.

55. The valve of claim 52 wherein said cylindrical wall comprises a lower sidewall and an upper sidewall and a taper connecting said lower sidewall and said upper sidewall, whereby said lower sidewall has a larger outside diameter than an outside diameter of said upper sidewall.

56. The valve of claim 55 wherein said upper sidewall and said lower sidewall have substantially equal inner diameters.

57. The valve of claim 52 further comprising a skirt extending from said body in a direction opposite said balloon.

58. The valve of claim 57 wherein said skirt has an outer diameter smaller than an outer diameter of said valve body, thereby providing a visual and tactile definition of an extent of said skirt, such that said skirt may be removed without removing material from said valve body.

59. The valve of claim 57 wherein said skirt is sized to frictionally fit within an open end of a dipping tube.

60. The valve of claim 52 wherein said valve is unitarily constructed from an elastomeric material.

61. The valve of claim 60 wherein said valve is unitarily constructed from silicone.

62. A valve constructed and arranged to be useable to form a balloon when said valve is subjected to a dip-coating process, said valve comprising:

a body;

a cylindrical sidewall extending from said body, said sidewall having a lower portion and an upper portion;

an end portion extending from said sidewall upper portion and defining an opening of a predetermined size;

whereby said predetermined opening is sized to allow a liquid, useable in said dip-coating process, to form a meniscus over said opening when said end portion is dipped in a quantity of said liquid and removed therefrom.

63. The valve of claim 62 wherein said lower portion has an outside diameter which is greater than an outside diameter of said upper portion.

64. The valve of claim 62 wherein said end portion curves inwardly as it extends from said sidewall upper portion such that said opening has an inner diameter which is smaller than an inner diameter of said upper portion.

65. The valve of claim 62 wherein said sidewall is integral with said body.

66. The valve of claim 62 further comprising a stem extending from said body, substantially concentric with, and circumjacent to, said sidewall.

67. A method of creating a channel through a valve useable in an implantable medical balloon, thereby creating an improved self-sealing characteristic of the valve when subjected to back pressure, the valve having a stem extending from the valve into an interior chamber of the balloon, the method comprising:

pushing a sharp, needle-like implement into said valve, opposite said stem, approximately along a longitudinal axis of said valve, until a sharpened end of said implement enters said stem;

bending said stem;

pushing said implement further until said implement exits a side of said stem, displaced from said axis, and enters said chamber;

removing said implement and releasing said stem, thereby allowing said stem to return to an original shape, and leaving a curved channel in said stem, due to said bending.

68. A method of forming a medical balloon, implantable into a human body, comprising:

providing a pool of silicone dispersion;

providing a valve portion having a body, an elongate cylindrical sidewall extending from said body, an inlet defined by said body opposite said sidewall, a skirt extending from said body opposite said sidewall, a valve member extending from said body inside and concentric with said sidewall, and an end portion extending from said sidewall, said end portion defining an opening;

attaching said valve portion skirt to a handling member;

dipping said end portion into said pool, thereby forming a meniscus over said opening when said valve portion is removed from said pool;

removing said end portion from said pool;

allowing said meniscus to harden such that said meniscus becomes integral with said end portion;

repeating said steps of dipping said end portion, removing said end portion from said pool, and allowing said meniscus to harden, until a meniscus plug of a desired thickness has formed over said opening;

partially vulcanizing said end portion;

dipping said valve portion into said pool to form a layer of silicone over said sidewall;

removing said valve portion from said pool;

allowing said layer to harden;

repeating the steps of dipping said valve portion, removing, and allowing said layer to harden, until a desired thickness of material has formed over said sidewall;

fully vulcanizing said balloon;

performing a piercing operation;

removing said balloon from said handling member;

performing an inflation test;

drying said balloon.

69. The method of claim 68 wherein said step of providing a valve portion comprises molding a valve portion out of silicone.

70. The method of claim 68 wherein attaching said valve portion skirt to a handling member comprises placing said skirt inside an open end of a dipping mandrel.

71. The method of claim 68 wherein allowing said layer to harden comprises spinning said valve portion around a central longitudinal axis.

72. The method of claim 68 wherein removing said balloon from said handling member comprises cutting said skirt off of said valve portion.

73. The method of claim 68 wherein partially vulcanizing said end portion comprises placing said valve portion into an oven at a predetermined temperature for a predetermined time.

74. The method of claim 73 wherein said predetermined temperature is less than 170C.

75. The method of claim 73 wherein said predetermined temperature is greater than 150C

76. The method of claim 73 wherein said predetermined temperature is approximately 160C.

77. The method of claim 73 wherein said predetermined time is greater than 5 minutes.

78. The method of claim 73 wherein said predetermined time is less than 20 minutes.

79. The method of claim 73 wherein said predetermined time is greater than 9 minutes

80. The method of claim 73 wherein said predetermined time is less than 11 minutes.

81. The method of claim 68 wherein fully vulcanizing said balloon comprises heating said balloon to a predetermined temperature for a predetermined time.

82. The method of claim 81 wherein said predetermined temperature is greater than 150C

83. The method of claim 81 wherein said predetermined temperature is less than 170C

84. The method of claim 81 wherein said predetermined temperature is approximately 160C

85. The method of claim 81 wherein said predetermined time is approximately 1 hour

86. The method of claim 68 wherein performing said inflation test comprises inflating said balloon with a fluid, inspecting said balloon for leaks, and deflating said balloon.

87. The method of claim 68 wherein said step of oven baking comprises placing said balloon in an oven at approximately 90C for approximately 60 minutes.

88. The method of claim 68 wherein the step of performing a piercing operation comprises:

pushing a sharp, needle-like implement through said inlet into said valve portion, opposite said stem, approximately along a longitudinal axis of said valve, until a sharpened end of said implement enters said stem;

bending said stem;

pushing said implement further until said implement exits a side of said stem, displaced from said axis;

removing said implement and releasing said stem, thereby allowing said stem to return to an original shape, and leaving a curved channel in said stem, due to said bending.